## REMARKS

By this amendment, Applicants have amended claims 32, 39 and 56 and new claims 59 and 60 have been added. Claims 32, 39 and 56 have been amended to include embodiments where the single nucleotide polymorphism (SNP) is immediately flanked by a 3' and 5' invariant nucleotide sequence. Support for this amendment can be found in the specification, for example, at page 11, lines 13-16, page 12, lines 5-8.

Applicants have also amended claim 56, which includes parentage testing in horses that are of the same breed that the Examiner suggests meets the written description requirement. (See Final Office Action, Item 10) Support for this amendment to claim 56 can be found, for example, at page 1, line 28, page 6, lines 30-35 and Examples 3 and 4. New claims 59 and 60 have been added, which includes a method of determining parentage in a mammal of the same species utilizing known SNPs in upper and lower strands of DNA, the SNPs are immediately flanked by invariant nucleotide sequences. Support can be found, for example, page 11, lines 13-16, page 12, lines 5-8 and Table 1-4. No new matter has been added. Applicants respectfully request entry of this amendment and reconsideration of the application.

**Rejection under 35 U.S.C. §112, First Paragraph: Written Description**

The Examiner rejected claims 32-58 under 35 U.S.C. §112, first paragraph for allegedly failing to comply with the written description requirement. Applicants respectfully traverse this rejection.

To establish a *prima facie* case of non-enablement, the Examiner has the burden of showing that the application does not teach how to make and use the claimed invention. *In re Wright,* 999 F.2d 1557, 1562 (Fed. Cir. 1999). Applicant respectfully submits that the Examiner has not met the burden.

The Examiner asserts (Office Action, Item 6) that claim 32 has been interpreted as encompassing an infinite number of SNPs in any and all regions of the genome of any mammal. Applicants respectfully disagree with the Examiner, nevertheless, to expedite

prosecution, Applicants have amended the claims to include that each single nucleotide polymorphic site is immediately flanked by a 3' and 5' invariant nucleotide sequence and that the polymorphic sites correspond to the same location of the genome. Thus, Applicants submit that this aspect of the rejection is rendered moot.

The Examiner also alleges that "six examples do not provide adequate written description of the claimed method where one would be able to determine any and all single nucleotide polymorphisms in any and all species of mammal." (Office Action, Item 9). Applicants have amended the claims to include that polymorphic site is immediately flanked by a 3' and 5' invariant nucleotide sequence and that the polymorphic sites correspond to the same location of the genome. Thus, the method utilizes specific types of SNPs at the same corresponding location on the genome or locus. Moreover, Examples 1-5 alone utilize 18 polymorphic loci in sixty horses, over 1,000 SNPs are utilized in the method described in the specification. Applicants submit the specification provides written description and fully enables the claims. The specification at pages 13-15, page 44, lines 29-36 and Examples 1-6 clearly discloses and enables conducting genetic analysis using SNPs from mammalian DNA. Applicants submit that genomic DNA is genomic DNA regardless of the species. All mammalian DNA comprises A, C, T and G. Thus, DNA does not chemically vary between species and the analysis of SNPs should not in any way depend on the source of the nucleic acid molecules.

Moreover, the amended and new claims are directed to use of SNPs in genetic analysis of genomic DNA obtained from mammals of **the same species**. The application as filed satisfies the written description requirement because it unambiguously conveys to those of skill in the art that the Applicants were in possession of the claimed invention as of the priority date. Applicants' insight that combinations of SNPs would be extremely useful as genetic markers and can be used for genetic analysis follows from their discovery regarding the distribution and density of SNPs in mammalian genomes. While the illustrative examples in the specification are directed to horse and human studies, one or ordinary skill in the art upon reading the specification would readily understand that

the methods and use of SNPs would be applicable to all species including mammals. Applicants have described this applicability throughout their specification. Therefore, it is respectfully submitted that the specification fully complies with the written description requirement for methods of identifying single nucleotide polymorphic sites in the genome of mammals of the same species. Accordingly, Applicants respectfully request withdrawal of this rejection.

The Examiner alleges that the specification does not provide adequate written description when one strand of DNA is analyzed. (Office Action, Item 9). Applicants respectfully submit that claims 56 and 59 include embodiments where both strands of DNA are analyzed. The Examiner also alleges that the specification fails to provide adequate written description to determine paternity on one breed of horse from another (Office Action, Item 10). Applicants respectfully point out that claim 56 has been amended to include parentage testing on the same breed of horse. Accordingly, Applicants respectfully request withdrawal of this rejection for claims 56 and 59.

**Rejections Under 35 U.S.C. § 112, First Paragraph: Enablement**

The Examiner rejected claims 32-58 under 35 U.S.C. §112, first paragraph for allegedly failing to comply with the enablement requirement. Applicants respectfully traverse this rejection.

While the Examiner alleges that the specification does present several examples directed to the analysis of equine and human DNA, the Examiner concludes that the six examples do not enable identification of mutations in any or all species of interest.

Applicants respectfully disagree with this rejection, and respectfully point out that the claims include methods for identifying single nucleotide polymorphic sites in the genome of mammals of the same species, not all species. Applicants have also amended the claims to include that polymorphic sites are immediately flanked by a 3' and 5' invariant nucleotide sequence and that the polymorphic sites correspond to the same location of the genome. Thus, the method utilizes specific types of SNPs at the same corresponding location on the genome or locus. Moreover, Examples 1-5 alone utilize 18 polymorphic loci in sixty horses, over 1,000 SNPs utilized in the method. Applicants

submit the specification provides written description and fully enables the claims. The specification at pages 13-15, page 44, lines 29-36 and Examples 1-6 clearly discloses and enables conducting genetic analysis using SNPs from mammalian DNA. Applicants submit that genomic DNA is genomic DNA regardless of the species. All mammalian DNA comprises A, C, T and G. Thus, DNA (A, C, T and G) does not chemically vary between species and the analysis of SNPs should not in any way depend on the source of the nucleic acid molecules.

As previously stated, the Examiner's reliance on *Genentech v. Novo Nordisk* ("*Genentech*") as analogous to the present case is misplaced. *Genentech* was decided on strikingly different facts. In *Genentech*, the claims recited a method for making human growth hormone in a fusion protein and cleaving the fusion protein to make the growth hormone. The patentees in *Genentech* tried to rely on the level of skill in the art to enable the claim, but at the time of filing the application it was ***not*** known in the art how to cleave a fusion protein to make growth hormone, ***where the cleaving of the fusion protein was the novel aspect of the claim***. In contrast, the novel aspect of the amended claims does not include claims to individual SNPs, but methods using the combinations of SNPs as useful genetic markers. Thus, *Genentech* sheds no light on any alleged written description or enablement issues with respect to the present claims. *Genentech* is simply inapplicable to the facts of this case.

Moreover, claims 59 and 60 have been added to include where the starting material involves known SNPs to determine the parentage testing. It is respectfully submitted, that the starting material is clearly provided by the specification. Applicants submit that the specification fully complies with the enablement requirement for methods of identifying single nucleotide polymorphic sites in the genome of mammals of the same species. Accordingly, Applicants respectfully request withdrawal of this rejection.

**Conclusion**

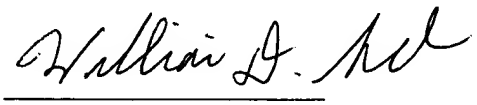
Reconsideration and allowance are respectfully solicited.

Applicants enclose a fee for 4-month extension of time. If any additional fees are due, or an overpayment has been made, please charge, or credit, our Deposit Account No.

11-0171 for such sum.

If the Examiner has any questions regarding the present application, the Examiner is cordially invited to contact Applicants' attorney at the telephone number provided below.

Respectfully submitted,



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